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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,034	05/25/2001	David Botstein	P2930R1C1	4767

7590 07/03/2003

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EXAMINER	
SPECTOR, LORRAINE	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Applicati n No.	Applicant(s)	
	09/866,034	BOTSTEIN ET AL.	
	Examiner	Art Unit	
	Lorraine Spector, Ph.D.	1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 May 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☒ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *none*.

   Claim(s) objected to: *none*.

   Claim(s) rejected: *27,28 and 32-35*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☒ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). *14*.

10. ☐ Other: _____

Lorraine Spector, Ph.D.
Primary Examiner
Art Unit: 1647

[redacted]

Continuation of 3. Applicant's reply has overcome the following rejection(s): rejection of claims under 112, second paragraph, and objection to mis-numbering of tables.

Continuation of 5. does NOT place the application in condition for allowance because: Neither applicants arguments nor the Goddard declaration are persuasive. As evidenced by the Heid paper cited by Goddard, the threshold value that is the basis for calculating Ct is set arbitrarily, based upon the variability of the baseline data (page 988). Note that contrary to the presentation of data in the specification as originally filed, the standard in the art as evidenced by page 990 of Heid et al. is to furnish both mean and standard deviation values. Thus, although this type of assay may be used in the art, the data presented in the specification are not sufficient to support applicants assertions of utility for cancer diagnosis, and applicants have not furnished facts or evidence to the contrary. Further, the Examiner maintains that aneuploidy of cancer cells is relevant, as merely showing that a particular gene (chromosome) is amplified in a particular cancer cell line is not probative of diagnostic utility, as (a) the cancer cell lines are not representataive of primary tumors, and are often more highly aneuploid than primary tumors; the presence of an aneuploid chromosome is not considered in the art, as evidenced by both the NCI website and the Sen publication, to be indicative of diagnostic use. Such aneuploidy may be a result, not a diagnostic factor of the cancer, and further has to be shown to be present in a statistically significant proportion of a particular type of cancer prior to being considered to have diagnostic utility Finally, applicnats argument at page 5, first full paragraph further confuses the issues; it would seem that applicants are urging that the samples were pre-selected for significant differences between normal and test samples. Further, the interpretations therein are not supported by the specification itself
Regarding the information disclosure statement: references 7-12 have been considered to the extent possible; without alignments between the sequences therein and those of the specification, the full relevance of the sequences cannot be determined.

[redacted]